

PHARMACY BOARD[657]**Notice of Intended Action**

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 124.201, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 10, “Controlled Substances,” Iowa Administrative Code.

The amendment was approved at the August 31, 2015, regular meeting of the Board of Pharmacy.

The proposed amendment rescinds current rule 657—10.38(124) and adopts new rule 657—10.38(124) temporarily designating certain identified substances as controlled substances, subject to the applicable security and control requirements and penalties provided for in the Iowa Controlled Substances Act (CSA), and removing one substance from the CSA, in conformance with recent scheduling actions of the federal Drug Enforcement Administration (DEA). The substances affected by this action include three synthetic cannabinoids and acetyl fentanyl, all of which are temporarily placed into Schedule 1 of the CSA. Synthetic cannabinoids are chemicals synthesized in laboratories and mimic the biological effects of THC, the main psychoactive ingredient in marijuana. These chemicals are much more potent than marijuana and are often marketed as herbal incense or potpourri. They have no accepted medical use in the United States and have been reported to produce adverse health effects, including acute and chronic abuse, addiction, and withdrawal. Acetyl fentanyl, a synthetic opioid, has been linked to at least 39 fatalities nationwide in 2013 and 2014 and poses an imminent hazard to public safety. There is currently no approved medical use for acetyl fentanyl, and it should be appropriately classified as a Schedule 1 controlled substance.

Also affected by this temporary action is naloxegol, a new molecular entity and derivative of naloxone. The Food and Drug Administration (FDA) recently approved naloxegol for marketing for the treatment of opioid-induced constipation in adults with chronic noncancer pain. Based on the FDA’s approval of naloxegol for marketing for an identified medical purpose and the lack of evidence of a high potential for abuse of this product, the Board concurs with the DEA’s decision to remove naloxegol from control under the CSA.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on December 29, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code section 124.201.

The following amendment is proposed.

Rescind rule 657—10.38(124) and adopt the following **new** rule in lieu thereof:

657—10.38(124) Temporary designation of controlled substances.

10.38(1) Amend Iowa Code subsection 124.204(9) by adding the following new paragraphs “g,” “h,” “i,” and “j”:

g. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: AB-CHMINACA.

h. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: AB-PINACA.

i. [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: THJ-2201.

j. N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: acetyl fentanyl.

10.38(2) Amend Iowa Code subsection 124.206(2), paragraph “*a*,” introductory paragraph, as follows:

a. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their respective salts, but including the following: